

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 April 2001 (12.04.2001)

PCT

(10) International Publication Number
WO 01/24690 A2

(51) International Patent Classification⁷: **A61B 5/00**

[GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts. SG12 ODP (GB).

(21) International Application Number: PCT/EP00/09291

(22) International Filing Date:
22 September 2000 (22.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9923273.8 1 October 1999 (01.10.1999) GB
0011029.6 9 May 2000 (09.05.2000) GB
0020541.9 22 August 2000 (22.08.2000) GB

(71) Applicant (for all designated States except US): **GLAXO GROUP LIMITED** [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **ANDERSON, Gregor, John, McLennan** [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts. SG12 ODP (GB). **BONNEY, Stanley, George** [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts. SG12 ODP (GB). **JONES, Anthony, Patrick** [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts. SG12 ODP (GB). **ROBERTSON, Duncan**

(74) Agent: **PIKE, Christopher, Gerard**; Pike & Co., Hayes loft, 68A Hayes Place, Marlow, Buckinghamshire SL7 2BT (GB).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— Without international search report and to be republished upon receipt of that report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **MEDICAMENT DELIVERY SYSTEM**

(57) Abstract: There is provided a system for the delivery of medicament comprising a medicament container; a dispensing mechanism for dispensing medicament from the medicament container; an electronic data management system; and a communicator for wireless communication with a network computer system to enable communication of data between the network computer system and the electronic data management system. The electronic data management system comprises a memory for storage of data; a microprocessor for performing operations on the data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.

WO 01/24690 A2

Medicament delivery system

5 The present invention relates to a system for the delivery of medicament having an electronic data management system. The system is capable of wireless communication with an entrypt to a network computer system to enable communication of data between the network computer system and the electronic data management system.

10 It is common prescribing practice for a doctor to prescribe a patient with medicament in a medicament dispenser together with instructions for patient administration of the medicament according to a defined treatment regime. The patient typically therefore, receives instructions relating to the correct use of the dispenser together with recommended dosing amounts, dose intervals and
15 treatment period. The patient is then trusted to follow the treatment regime as set by the doctor.

A limitation associated with this practice is that the treatment regime is set at the time of prescription and can therefore not account for changes in the patient's
20 condition over the treatment period. A further limitation associated with this practice is that the onus is on the patient to comply with the doctor's instructions. Occasionally, patients will forget to take the medicament or will vary the treatment regime in an unpredictable manner with possible consequences for the success of the treatment.

25 A variation on the above-described prescribing practice involves the use by a patient of a diagnostic device which enables data relating to their medical condition to be gathered on a regular basis. This data may for example, be collected prior to administration of any medicament and a correct dose amount
30 calculated on the basis of the diagnostic data. An example of this practice would be that of a diabetic who checks their blood-sugar levels in order to calculate a required dose of insulin.

35 In developments of the practice variation, the diagnostic device may be integrated with the delivery system. Information relating to the patient's condition

and usage of the dispenser may thus be displayed to the patient to enable the better management of their medical condition. The information may further be stored in a memory such that it may be recalled at a later time to enable historic analysis of the progress of the condition and effect of the treatment. Dispensers
5 employing electronic data management systems have been proposed for this purpose.

US-A-5,363,842 describes an inhalation device for use in delivering inhalable medicament. The device enables data relating to the patient's breathing pattern
10 to be collected, analysed and displayed to the patient. The data is stored in a memory for download to a workstation at the clinic.

WO99/35588 describes a method for managing the administration of medicine and in particular, monitoring patient compliance with a prescribed treatment
15 regime. The method relies on input of patient data to a central computer workstation. The central computer workstation calculates and transmits dosage data to a dispensing device via a communications link. The dispensing device delivers drug in accord with the dosage data.

The Applicants have now developed an improved system for the delivery of medicament which employs an electronic data management system. The system is capable of wireless communication with a network computer system to enable communication of data between the network computer system and the electronic data management system. The system therefore, provides the advantage of
25 enabling data transfer with a network of computers, which network can be made accessible to diverse remote information sources, which may in turn be networked together for cross-transfer of data. The patient therefore, has ready access to diverse, possibly inter-connected, remote information sources capable of providing disease management information. In turn, the system can feed
30 information, such as compliance information, back to any remote information source having access to the network computer system. The system can also be integrated with a healthcare management system for remote prescribing or remote variation or control of the prescribing regime. The healthcare management system will typically be under the control of a healthcare
35 professional such as a doctor.

According to one aspect of the present invention there is provided a system for the delivery of medicament comprising a medicament container; a dispensing mechanism for dispensing medicament from the medicament container; an
5 electronic data management system; and a communicator for wireless communication with a network computer system to enable transfer of data between the network computer system and the electronic data management system.

10 The elements of the system herein will in one preferred embodiment be comprised within a single device having medicament delivery, electronic data management and communications capability. The device is preferably a portable or hand held device.

15 In another preferred embodiment, the electronic data management and communications aspects of the system will be comprised as a distinct control unit which is associable with the medicament delivery aspects of the system. The control unit may for example form a snap-fit module which receives or is
20 receivable by a separate medicament delivery device.

20 The network computer system is typically located at, and under the control of, a healthcare provider or manager such as a doctor's practice, a hospital or healthcare management centre. It is an advantage of the system herein, that the network computer system may be located geographically distant from the
25 patient but be wirelessly accessible to the patient via the system of the present invention.

The electronic data management system comprises a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter
30 for transmitting a signal relating to the data or the outcome of an operation on the data.

Either the network computer system or the communicator may initiate data transfer. Preferably, the communicator enables two-way transfer of data

between the network computer system and the electronic data management system.

Suitably, the data is communicable between the network computer system and the electronic data management system in encrypted form. All suitable methods of encryption or partial encryption are envisaged. Password protection may also be employed. Other methods of ensuring data security are envisaged including the use of systems reliant on the use of secure token codes.

Suitably, the communicator employs radiofrequency or optical (e.g. infra red or ultra violet) signals.

In one aspect, the communicator communicates with the network computer system via a gateway thereto. Communication will typically involve the use of a suitable communications protocol.

In another aspect, the system (device) is provided with an embedded network server to enable it to be comprised directly within the network system, typically using IP protocol. The embedded network server will have hardware and software components and for example comprise an HTTP (web) server, an FTP (file) server or an SMTP (mail) server. The embedded network server will typically be provided with a unique network address such as a web-site address, an e-mail address or a file transfer protocol address. The so-enabled system (device) may also have the capability to form local area networks with other similarly enabled systems (devices) to enable local transfer of data therebetween.

Suitably, the communicator communicates with network computer system via a second communications device. The second communications device may itself comprise an embedded web server. Preferably, the second communications device is a telecommunications device, more preferably a cellular phone or pager. Preferably, the communicator communicates with the second communications device using spread spectrum radiofrequency signals. A suitable spread spectrum protocol is the Bluetooth (trade mark) standard which employs rapid (e.g. 1600 times a second) hopping between plural frequencies

(e.g. 79 different frequencies). The protocol may further employ multiple sending of data bits (e.g. sending in triplicate) to reduce the effect of interference.

5 In another aspect, the communicator communicates with the second communications device using an infra red data communications standard (e.g. IrDA).

10 In one aspect, the network computer system comprises a public access network computer system. The Internet is one suitable example of a public access network computer system, wherein the entryptment thereto is typically managed by an Internet service provider. The public access network computer system may also form part of a telecommunications system, which may itself be either a traditional copper wire system, a cellular system or an optical or microwave network.

15 In another aspect, the network computer system comprises a private access network computer system typically comprising a private entryptment system. The private access network system may for example, comprise an intranet or extranet which may for example, be maintained by a health service provider or
20 medicament manufacturer. The private access network system may for example include password protection; a firewall; and suitable encryption means.

Suitably, different levels of access authorisation to the network computer system will be provided to different authorised users. Example of authorised users may
25 include the patient, a healthcare professional such as a doctor or nurse, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof.

30 Suitably, the communicator enables communication with a user-specific network address in the network computer system. The user-specific network address may be selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address. The network address may be pre-assigned or it may be dynamically assigned at the time of communication.

Suitably, the user-specific network address is accessible to a remote information source such that information from said remote information source can be made available thereto. More preferably, information from the user-specific network address can be made available to the remote information source.

5

In one aspect, the remote information source is a medicament prescriber, for example a doctor's practice. Information transferred from the medicament prescriber may thus, comprise changes to prescription details, prescription updates or training information. Information transferred to the medicament prescriber may comprise compliance information, that is to say information relating to the patient's compliance with a set-prescribing programme. Patient performance information relating for example, to patient-collected diagnostic data may also be transferred to the medicament prescriber. Where the dispenser is an inhaler for dispensing medicament for the relief of respiratory disorders examples of such diagnostic data would include breath cycle data or peak flow data.

10
15

In another aspect, the remote information source is a pharmacy. Information transferred from the pharmacy may thus, comprise information relating to the medicament product. Information sent to the pharmacy may thus include prescription requests, which have been remotely pre-authorized by the medicament prescriber.

20

In a further aspect, the remote information source is an emergency assistance provider, for example a hospital accident and emergency service or an emergency helpline or switchboard. The information may thus, comprise a distress or emergency assist signal which requests emergency assistance.

25

In a further aspect, the remote information source is a manufacturer of medicament or medicament delivery systems. Information transferred to the system may thus, comprise product update information. The system may also be configured to feed information back to the manufacturer relating to system performance.

30

In a further aspect, the remote information source is a research establishment. In a clinical trials situation, information may thus be transferred relating to the trials protocol and information relating to patient compliance fed back to the research establishment.

5

In a further aspect, the remote information source is an environmental monitoring station. Information relating to weather, pollen counts and pollution levels may thus be made accessible to the system.

10 The communicator may also enable communication with a public-access network address such as a public web-site on the Internet.

Suitably, the system additionally comprises a wired or wireless datalink for linking to a local data store such as a personal computer or set-top box to enable communication of data between the local data store and the microprocessor.

15

Preferably, the datalink comprises an infrared emitter and sensor.

Suitably, the system additionally comprises a data input system for user input of data to the electronic data management system. More preferably, the data input system comprises a man machine interface (MMI) preferably selected from a keypad, voice recognition interface, graphical user interface (GUI) or biometrics interface.

20

Suitably, the system additionally comprises a display for display of data from the electronic data management system to the user. The display may for example, comprise a screen such as an LED or LCD screen.

25

Suitably, the electronic data management system includes a predictive algorithm or look-up table for calculating the optimum amount of medicament to dispense.

30

Suitably, the memory includes a dose memory for storing dosage data and reference is made to the dose memory in calculating the optimum amount of medicament to dispense.

Suitably, the system additionally comprises a selector for selecting the amount of medicament to dispense from said dispensing mechanism. The selector may thus be employed to vary the medicament dose for dispensing from the dispensing mechanism.

5

In one aspect, the selector is manually operable.

In another aspect, the selector is operable in response to a signal from the transmitter.

10

Suitably, the selector comprises a timing mechanism for varying the time interval of actuation of the dispensing mechanism.

15

Alternatively, the selector comprises a metering mechanism between the medicament container and the dispensing mechanism for metering a variable quantity of medicament for dispensing.

20

Alternatively, the selector comprises a multiple-fire mechanism for multiple actuation of the dispensing mechanism, wherein each actuation releases a portion of the optimum amount of medicament. Successive actuations may be pulsed, for example such that the time intervals between actuations may be based on arithmetic or geometric progressions.

25

Suitably, the system additionally comprises a detector for detecting dispensing from the medicament container, wherein said detector communicates dispensing data to the electronic data management system.

30

Suitably, the system additionally comprises a geographic positioning system such as a global positioning system or a system which relies on the use of multiple communications signals and a triangulation algorithm.

35

In one aspect, the system is suitable for the delivery of inhalable medicament and additionally comprises a sensor which senses the breath of a user, wherein the sensor communicates breath data to the electronic data management system.

In one aspect, the sensor comprises a breath-movable element which is movable in response to the breath of a patient. More preferably, the breath-movable element is selected from the group consisting of a vane, a sail, a piston
5 and an impeller.

In another aspect, the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

10 In a further aspect, the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

In a further aspect, the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user. The temperature of the
15 inhaled and exhaled part of the breath cycle varies and may, thus, be used as a measurement tool.

In a further aspect, the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user. The moisture content of the
20 inhaled and exhaled part of the breath cycle varies and this also may be used as a measurement tool.

In a further aspect, the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user. The chemical profile
25 of the inhaled and exhaled part of the breath cycle varies and this further may be used as a measurement tool.

Suitably, the breath data includes breath cycle data or peak flow data.

30 Suitably, the system additionally comprises an actuator for actuating the dispensing mechanism, said actuator being actuable in response to a trigger signal from the transmitter.

Suitably, the electronic data management system includes a predictive algorithm
35 or look-up table for deriving from the breath data when to transmit the trigger

signal. For example, a real-time analysis of the patient breath waveform may be made and the trigger point derived by reference to that analysed waveform.

5 In one preferred aspect, the medicament container is an aerosol container and the dispensing mechanism is an aerosol valve.

10 In another preferred aspect, the medicament container is a dry-powder container, that is to say a container suitable for containing medicament in dry-powder form.

Suitably, the actuator comprises an energy store for storing energy which energy is releasable to actuate the dispensing mechanism of the medicament container. The energy store comprises in preferred aspects, a biasable resilient member such as a spring, a source of compressed fluid such as a canister of compressed
15 gas or a battery. Chemical energy sources are also suitable and might include chemical propellant or ignition mixtures. Other sources might include physical explosives such as liquefied or solidified gas in a canister which burst when heated or exposed to the atmosphere.

20 The system may additionally comprise a safety mechanism to prevent unintended multiple actuations of the actuator. The patient is thereby protected from inadvertently receiving multiple doses of medicament in a situation where they take a number of short rapid breaths. More preferably, the safety mechanism imposes a time delay between successive actuations of the actuator.
25 The time delay is typically of the order of from three to thirty seconds.

An actuation counter which can be mechanical or electronic may be provided to the system.

30 A medicament dispensing counter, such as a dose counter, may be provided to the system. This may be mechanical or electronic. The counter may be coupled to a visual display to provide feedback to the patient as to amount of drug released or remaining in the container.

A manual override can be provided to the system for use in the event of emergency or system failure.

According to another aspect of the present invention there is provided a data
communicator for use with a medicament dispenser comprising an electronic
data management system; a communicator for communicating wirelessly with a
network computer system to enable communication of data between the network
computer system and the microprocessor; and a coupling mechanism for
coupling the data communicator to the medicament dispenser.

The electronic data management system comprises a memory for storage of
data; a microprocessor for performing operations on said data; and a transmitter
for transmitting a signal relating to the data or the outcome of an operation on
the data. The memory may comprise a non-volatile memory chip (e.g. an
EEPROM or FLASH memory chip) which is capable of storing data when the
electronic data management system is turned off.

According to another aspect of the present invention there is provided a kit of
parts comprising a data communicator as described above and a medicament
dispenser comprising a medicament container; and a dispensing mechanism for
dispensing medicament from the medicament container.

The data communicator may for example, be mechanically coupled to the
medicament dispenser by any suitable mechanical mechanism including grip
mechanisms and snap-fit mechanisms. In a preferred aspect, the data
communicator forms a snap-in module and the dispenser is shaped to be
receivable by or for receipt of the module.

In aspects, the data communicator or any distinct device aspects of the system
may be adapted to be worn on the body of the user. Examples would include belt
attachable devices, devices in the form of watches for wrist or leg attachment
and devices attachable as jewellery. Suitable body attachment means will be
incorporated as required.

According to further aspects of the present invention there are provided methods for use of the system herein and software for the implementation thereof.

5 Embodiments of systems according to the invention will now be described with reference to the accompanying drawings in which:

Figure 1. is a schematic representation of a first system in accord with the present invention;

10 Figure 2. is a schematic representation of a second system in accord with the present invention;

15 Figures 3. and 4. are schematic representations of third and fourth systems in accord with the present invention in which the electronic data management system integrates with a system for electronic prescription of medicament;

Figure 5. is a system diagram of a third system in accord with the present invention;

20 Figure 6. is a system diagram of a central controller unit for use in accord with the present invention; and

Figure 7. is a system diagram of a patient electronic data manager for use in accord with the present invention.

25 Figure 1. shows a standard-form metered dose inhaler for the delivery of inhalable medicament comprising a tubular housing 10 in which an aerosol container 12 is located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. A dispensing outlet 14 leads laterally from the closed end of the housing 10. In the embodiment illustrated, the outlet 14 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if
30 desired, be designed as a nozzle for insertion into the patient's nostril.

The aerosol container 12 is located in the housing 10 so that one end protrudes from the open top of the housing 10. The aerosol container 12 has an outlet valve stem (not visible) at one end which connects with a support (not shown) in the housing 10. To dispense the dose, the protruding portion of the aerosol container 12 is depressed to move the container 12 relative to the valve stem to open the valve and dispense medicament into the outlet 14 from which it can be inhaled by a patient.

The dispenser includes an electronic data management system in the form of an integrated circuit preferably integrated into one or more integrated circuit chips and comprised within the housing (not visible). The user may access the electronic data management system by use of push-buttons 20 and toggle menu-button 24. Display 30 allows for display of menu choices and data from the electronic data management system. The dispenser communicates via communications transceiver 40 to network computer system 50. The network computer system 50 comprises a secure extranet computer system. Remote information sources 60, 62, 64, 66, 68 also have access to the extranet. In more detail, the remote information sources comprise a medicament prescriber 60, a pharmacy 62, a weather monitoring station 64, a pollution monitoring station 66 and a medicament manufacturer 68. Two-way data transfer is possible between the electronic data management system and the network computer system 50 via the communications transceiver 40. Information transfer is thus possible between the electronic data management system and any of the remote information sources 60, 62, 64, 66, 68. Information received from any of the remote information sources 60, 62, 64, 66, 68 may be utilised by the electronic data management system to vary the recommended medicament dose for delivery to the patient.

Figure 2. shows a variation of the system of Figure 2. The system comprises standard-form metered dose inhaler for the delivery of inhalable medicament comprising tubular housing 110, an aerosol container 112 and dispensing outlet 114. Operation of the inhaler is as described above with reference to Figure 1.

The dispenser includes an electronic data management and communications system 140 comprised within the housing 110. Display 130 allows for limited

display data from the electronic data management system. The dispenser readily communicates via chip 140 to palmtop computer 170. The communication is via spread spectrum radiofrequency signals operable over a relatively short range (e.g. up to ten metres). The palmtop computer 170 has a more sophisticated display 172 including a graphical user interface comprising menu-entry screens from which selections may be made using toggle menu-button 174.

The user accesses the electronic data management system 140 of the dispenser through the palmtop computer 170. The palmtop computer 170 itself can communicate through a telecommunications link with network computer system 150. The network computer system 150 comprises a secure extranet computer system. As in Figure 1, remote information sources may also have access to the extranet. Two-way data transfer is possible between the electronic data management system and the network computer system 150 via the communications links with the palmtop computer 170. Information transfer is thus possible between the electronic data management system 140, palmtop computer 170 and any of the remote information sources.

Figure 3 shows a system herein in which patient electronic data management system 240 communicates wirelessly with geographically distant network computer system 250. The network computer system 250 is itself accessible (.e. wirelessly or via a modem link) by the system of a medicament prescriber 260 (e.g. a doctor's surgery system) and by the system of a pharmacist 262.

The system of Figure 3 may be employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data management system 240 communicates data relating to the medical condition of the patient to the network computer system 250. The medicament prescriber 260 accesses this data e.g. by wirelessly by use of a palmtop communications and data management device and makes a judgement as to prescription needs. If a new prescription is needed the prescriber sends a 'prescription authorisation' signal to the network computer system 250. The pharmacist 262 then accesses the network computer system to receive the 'prescription authorisation' signal which authorises them to make up the prescription for the patient.

The system of Figure 4 is a variation of the system of Figure 3 in which patient electronic data management system 340 communicates wirelessly with geographically distant network computer system 350. The network computer system 350 is itself accessible by the system of a medicament prescriber 360 (e.g. via a modem-enabled personal computer of a doctor). The prescriber system 360 may also access second network computer system 354 which is accessible by the system of a pharmacist 362. In an alternative herein, the second computer system 354 may be integral with the system of the pharmacist 362 or be a dedicated secure prescription system accessible only to the prescriber and the pharmacist.

The system of Figure 4 is employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data management system 340 communicates data relating to the medical condition of the patient to the network computer system 350. The medicament prescriber 360 wirelessly accesses this data and makes a judgement as to prescription needs. If a new prescription is needed the prescriber sends a 'prescription authorisation' signal to the second network computer system 354. The pharmacist 362 then accesses the network computer system to receive the 'prescription authorisation' signal which authorises the pharmacist to make up the prescription for the patient.

Figure 5. shows a representative system herein comprising an electronic patient data manager 440 comprised within a drug delivery system (not shown) which would be under the control of the patient. Associated with the patient electronic data manager 440 there is a patient communicator 442 which is capable of wireless communication with a network computer system 450. The system also comprises an authorised user interface 480 having associated authorised user communicator 482 which is capable of communicating with the network computer system 450. Central controller unit 490 is in two-way communication with the network computer system 450.

The system of Figure 5. is shown in patient 'data upload mode' wherein patient data 444 is wirelessly communicated from the patient data manager 440 to the network. It may be appreciated that any patient can also communicate requests for data to the network 450 and receive responses thereto via the patient

communicator 442 and patient data manager 440. The system is also shown in authorised user 'enquiry mode' in which a database enquiry 484 is communicated to the network computer system 450 and a response received 486 via the authorised user communicator 482 to the authorised user interface 480.

Figure 6. shows the structure of the central controller 590 in more detail. The central controller includes a data storage device 591, central processor (CPU) 592, cryptographic processor 593, RAM 594, ROM 595, payment processor 596, operating system 597 and billing processor 598.

The components of the central controller 590 must be selected to be capable of handling sufficiently large volumes of data. The data storage devices, processors and operating system and other components may be selected from those commercially available.

The data storage device 591 is partitioned to include plural databases. The databases comprise a patient data database 548 which comprises data communicated from the patient electronic data manager; a patient database 549 which includes patient details such as name, address and possibly medical history; an authorised user database 589 which includes details of authorised users of the system; a billing database 561 for use in billing authorised users on retrieval of data; a payment database 563 for use in payment of other authorised users in return for data provided; and a crypto key database 565 comprising encryption information.

It will be appreciated that various parts of the system are designed to co-operate with each other in use. For example, the cryptographic processor 593 will access the crypto key database 565 to enable performance of user authentication. Together these crypto elements may form a secure access gateway to the patient data database.

Figure 7 shows a patient electronic data manager 610 comprised with a respiratory drug delivery system (not shown). The electronic data manager 610 comprises a central processor unit (CPU) 621; RAM 622; ROM 623 and a

cryptographic processor 624. The CPU 621 receives patient data from sensor 615 which may for example be a breath sensor or a sensor detecting actuation of the respiratory drug delivery system. The received data is storable in data storage device 625 which includes two databases, one for storage of patient medical data 626 and one for storage of personal patient data 628. The CPU 621 is associated with man machine interface 620 for receipt of patient input commands and display driver 632 and display 630 for display of information to the patient. The CPU 621 is further associated with communications port 640 which links via wireless communications link 642 to the central controller 690 of a network computer system (not shown).

It will be appreciated that the basic structure of the patient electronic data manager 610 of Figure 7 can act as an authorised data communicator for making enquiry requests to the databases on the network computer system and receiving responses therefrom. It will also be appreciated that the structure of the patient electronic data manager could be adapted by removal of the sensor 615 to form a non-patient authorised data communicator which would not be comprised within a respiratory drug delivery system.

The system of the invention is in one aspect suitable for dispensing medicament for the treatment of respiratory disorders such as disorders of the lungs and bronchial tracts including asthma and chronic obstructive pulmonary disorder (COPD).

Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (eg as the sodium salt), ketotifen or nedocromil (eg as the sodium salt); antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-inflammatories, e.g., beclomethasone (eg as the dipropionate ester), fluticasone (eg as the propionate ester), flunisolide, budesonide, rofleponide, mometasone eg as the furoate ester), ciclesonide, triamcinolone (eg as the acetonide) or 6α , 9α -difluoro- 11β -hydroxy- 16α -methyl-3-oxo- 17α -propionyloxy-androsta-1,4-diene- 17β -carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester; antitussives, e.g., noscapine;

bronchodilators, e.g., albuterol (eg as free base or sulphate), salmeterol (eg as xinafoate), ephedrine, adrenaline, fenoterol (eg as hydrobromide), formoterol (eg as fumarate), isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol (eg as acetate), reproterol (eg as hydrochloride), rimiterol, terbutaline (eg as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; adenosine 2a agonists, eg 2R,3R,4S,5R)-2-[6-Amino-2-(1S-hydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5-(2-ethyl-2H-tetrazol-5-yl)-tetrahydro-furan-3,4-diol (e.g. as maleate); α_4 integrin inhibitors eg (2S)-3-[4-({4-(aminocarbonyl)-1-piperidinyl}carbonyl)oxy]phenyl]-2-(((2S)-4-methyl-2-{{2-(2-methylphenoxy) acetyl}amino}pentanoyl)amino] propanoic acid (e.g as free acid or potassium salt), diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (eg as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon; vaccines, diagnostics, and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) or formoterol (eg as the fumarate salt) in combination with an anti-inflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate) or budesonide. A particularly preferred combination is a combination of fluticasone propionate and salmeterol, or a salt thereof (particularly the xinafoate salt). A further combination of particular interest is budesonide and formoterol (e.g. as the fumarate salt).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

5

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use

10

claims and may include, by way of example and without limitation, one or more of the following claims:

CLAIMS:

1. A system for the delivery of medicament comprising

5 a medicament container;

a dispensing mechanism for dispensing medicament from the medicament container;

10 an electronic data management system comprising

a memory for storage of data;

15 a microprocessor for performing operations on said data; and

a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data; and

20 a communicator for wireless communication with a network computer system to enable transfer of data between the network computer system and the electronic data management system.

25 2. A system according to claim 1, wherein the communicator enables two-way transfer of data between the network computer system and the electronic data management system.

30 3. A system according to either of claims 1 or 2, wherein the data is communicable between the network computer system and the electronic data management system in encrypted form.

4. A system according to any of claims 1 to 3, wherein the communicator employs radiofrequency or optical signals.

35 5. A system according to any of claims 1 to 4, wherein the communicator communicates with the network computer system via a gateway thereto.

6. A system according to any of claims 1 to 4, wherein the communicator includes an embedded network server.

5 7. A system according to any of claims 1 to 6, wherein the communicator communicates with the network computer system via a second communications device having telecommunications capability.

10 8. A system according to claim 7, wherein the telecommunications device comprises a cellular phone or pager.

15 9. A system according to any of claims 6 to 8, wherein the communicator communicates with the second communications device using spread spectrum radiofrequency signals.

10. A system according to any of claims 1 to 9, wherein the network computer system comprises a public access network computer system.

20 11. A system according to any of claims 1 to 9, wherein the network computer system comprises a private access network computer system.

25 12. A system according to any of claims 1 to 11, wherein the communicator enables communication with a user-specific network address in the network computer system.

13. A system according to claim 12, wherein the user-specific network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address.

30 14. A system according to either of claims 12 or 13, wherein the user-specific network address is accessible to a remote information source such that information from said remote information source can be made available thereto.

15. A system according to claim 14, wherein information from the user-specific network address can be made available to the remote information source.

5 16. A system according to either of claims 14 or 15, wherein the remote information source is a medicament prescriber.

17. A system according to either of claims 14 or 15, wherein the remote information source is a pharmacy.

10

18. A system according to either of claims 14 or 15, wherein the remote information source is an emergency assistance provider.

15 19. A system according to either of claims 14 or 15, wherein the remote information source is a manufacturer of medicament or medicament delivery systems.

20. A system according to either of claims 14 or 15, wherein the remote information source is a research establishment.

20

21. A system according to claim 15, wherein the remote information source is an environmental monitoring station.

25 22. A system according to any of claims 1 to 21, additionally comprising a datalink for linking to a local data store to enable communication of data between the local data store and the microprocessor.

23. A system according to claim 22, wherein the datalink comprises an infrared emitter and sensor.

30

24. A system according to either of claims 22 or 23, wherein the local data store comprises a personal computer or set-top box.

25. A system according to any of claims 1 to 24, additionally comprising a data input system for user input of data to the electronic data management system.

5 26. A system according to claim 25, wherein said data input system comprises a man machine interface selected from the group consisting of a keypad, voice recognition interface, graphical user interface (GUI) or biometrics interface.

10 27. A system according to any of claims 1 to 26, additionally comprising a display for display of data from the electronic data management system to the user.

15 28. A system according to any of claims 1 to 27, wherein said electronic data management system includes a predictive algorithm or look-up table for calculating the optimum amount of medicament to dispense.

20 29. A system according to claim 28, wherein the memory includes a dose memory for storing dosage data and reference is made to the dose memory in calculating the optimum amount of medicament to dispense.

25 30. A system according to any of claims 1 to 29, additionally comprising a selector for selecting the amount of medicament to dispense from said dispensing mechanism.

31. A system according to claim 30, wherein the selector is manually operable.

30 32. A system according to claim 31, wherein the selector is operable in response to a signal from the transmitter.

35 33. A system according to any of claims 1 to 32, additionally comprising a detector for detecting dispensing from the medicament container, wherein said detector communicates dispensing data to the electronic data management system.

34. A system according to any of claims 1 to 33, additionally comprising a geographic positioning system.

5 35. A system for the delivery of inhalable medicament according to any of claims 1 to 34 additionally comprising a sensor which senses the breath of a user, wherein the sensor communicates breath data to the electronic data management system.

10 36. A system according to claim 35, wherein said sensor comprises a breath-movable element which is movable in response to the breath of a patient.

37. A system according to claim 36, wherein said breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

15 38. A system according to claim 35, wherein the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

20 39. A system according to claim 35, wherein the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

40. A system according to claim 35, wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the
25 breath of a user.

41. A system according to claim 35, wherein the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user.

30 42. A system according to claim 35, wherein the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user.

43. A system according to any of claims 35 to 42, wherein said breath data includes breath cycle data.

44. A system according to any of claims 35 to 42, wherein said breath data includes peak flow data.

45. A system according to any of claims 35 to 44, additionally comprising an actuator for actuating the dispensing mechanism, said actuator being actuatable in response to a trigger signal from the transmitter.

46. A system according to claim 45, wherein the electronic data management system includes a predictive algorithm or look-up table for deriving from the breath data when to transmit the trigger signal.

47. A system according to any of claims 35 to 46, wherein said medicament container is an aerosol container and the dispensing mechanism is an aerosol valve.

48. A system according to any of claims 35 to 46, wherein said medicament container is a dry-powder container.

49. A system according to any of claims 45 to 48, wherein said actuator comprises an energy store for storing energy which energy is releasable to actuate the dispensing mechanism of the medicament container.

50. A data communicator for use with a medicament dispenser comprising an electronic data management system comprising

a memory for storage of data;

a microprocessor for performing operations on said data; and

a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data;

a communicator for communicating wirelessly with a network computer system to enable communication of data between the network computer system and the microprocessor; and

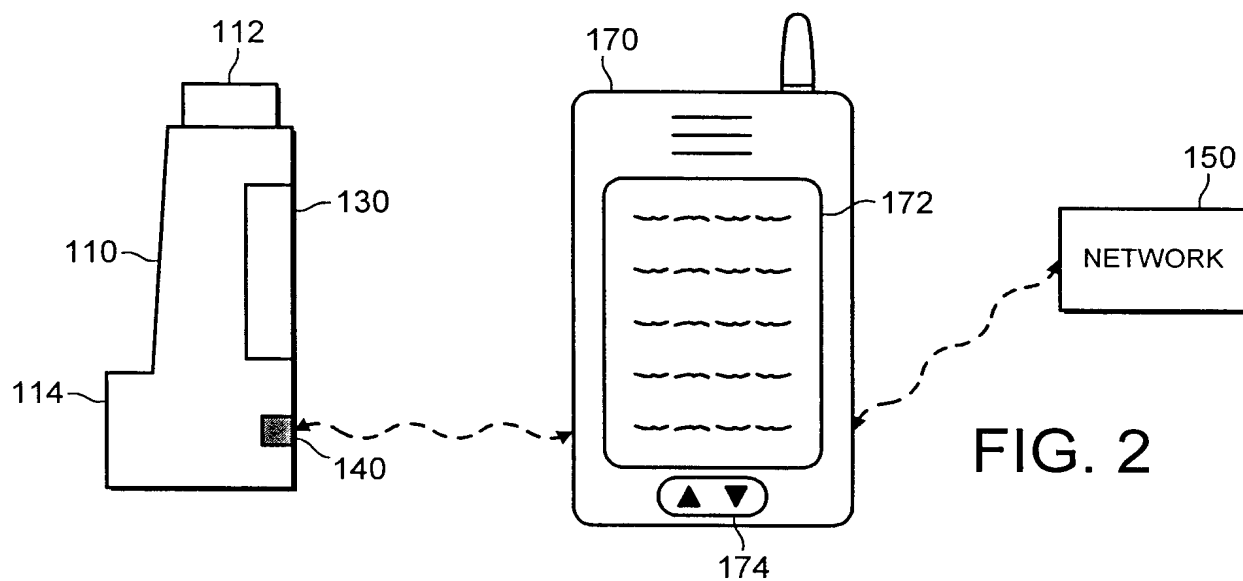
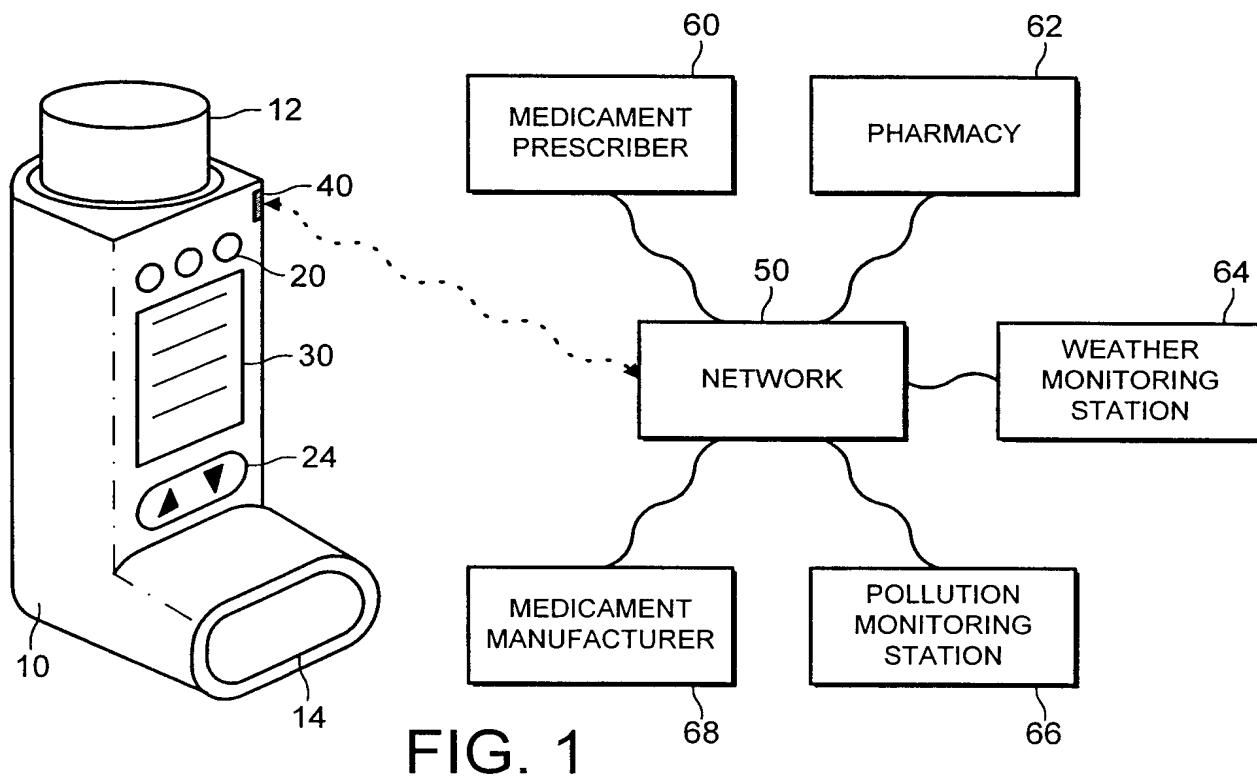
5

a coupling mechanism for coupling the data communicator to the medicament dispenser.

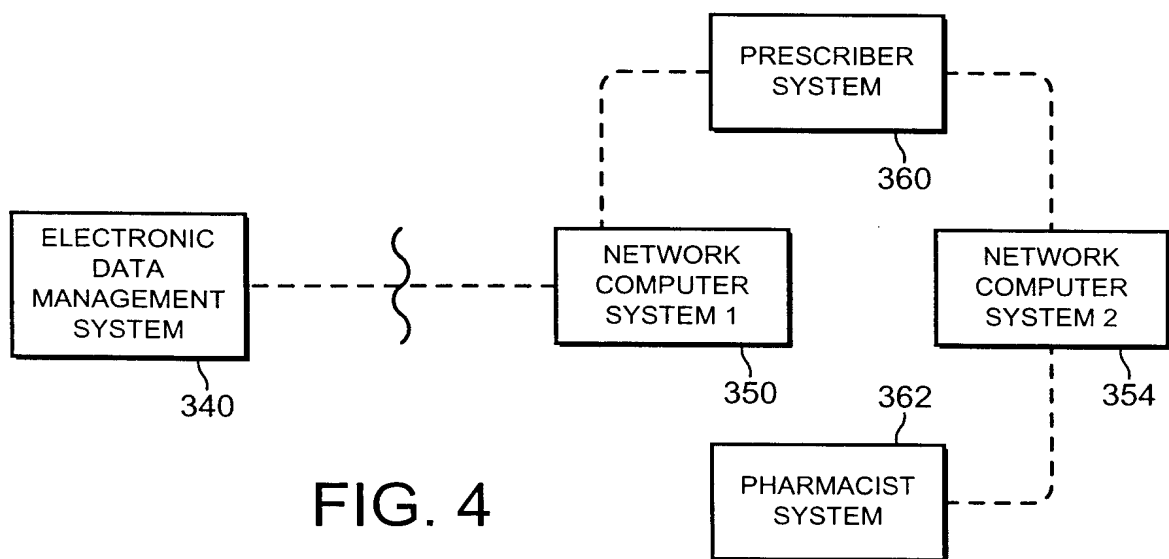
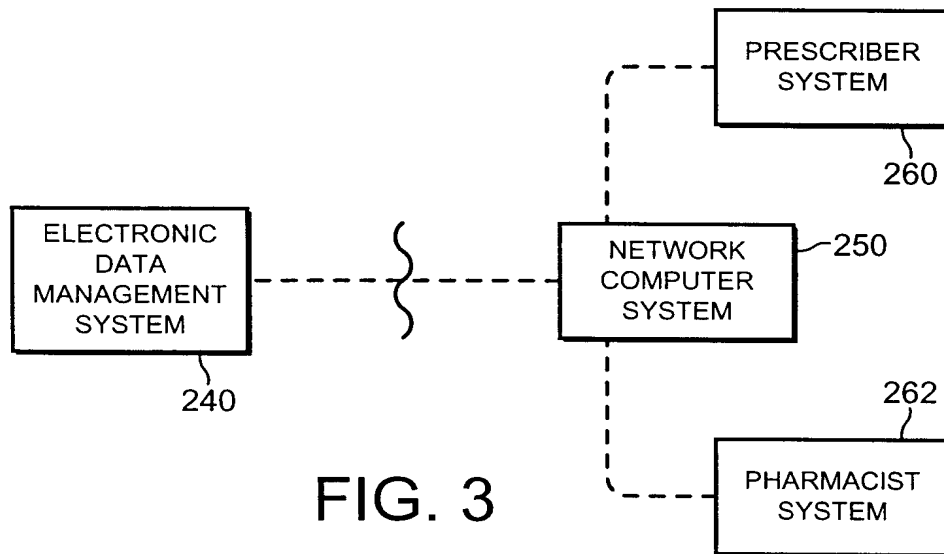
10

51. Kit of parts comprising a data communicator according to claim 50 and a medicament dispenser comprising a medicament container; and a dispensing mechanism for dispensing medicament from the medicament container.

1 / 5



2 / 5



3 / 5

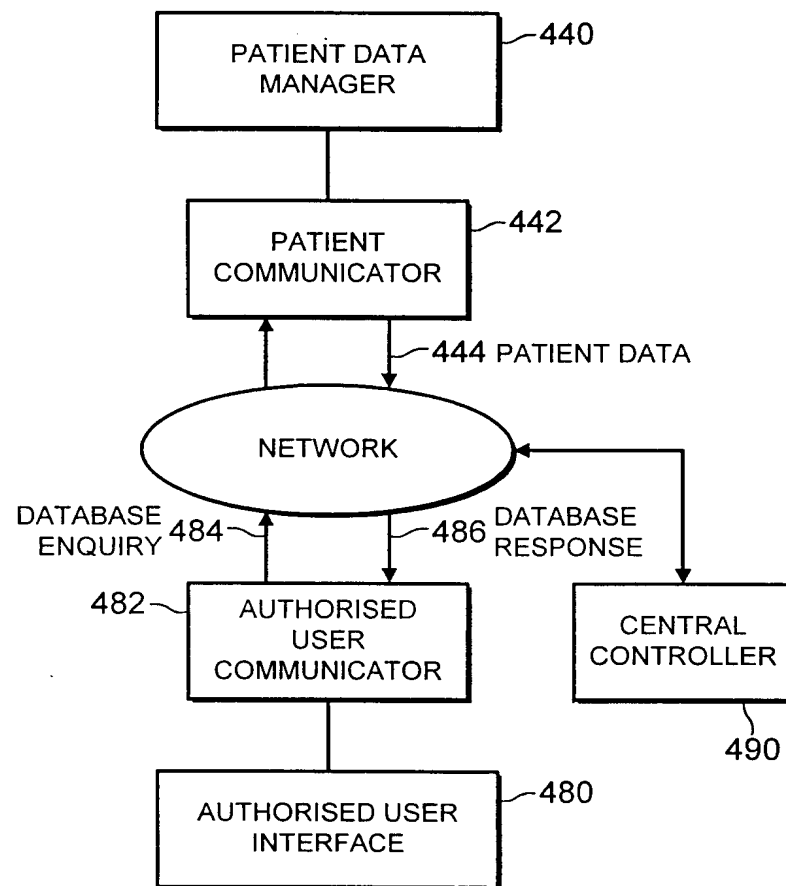


FIG. 5

4 / 5

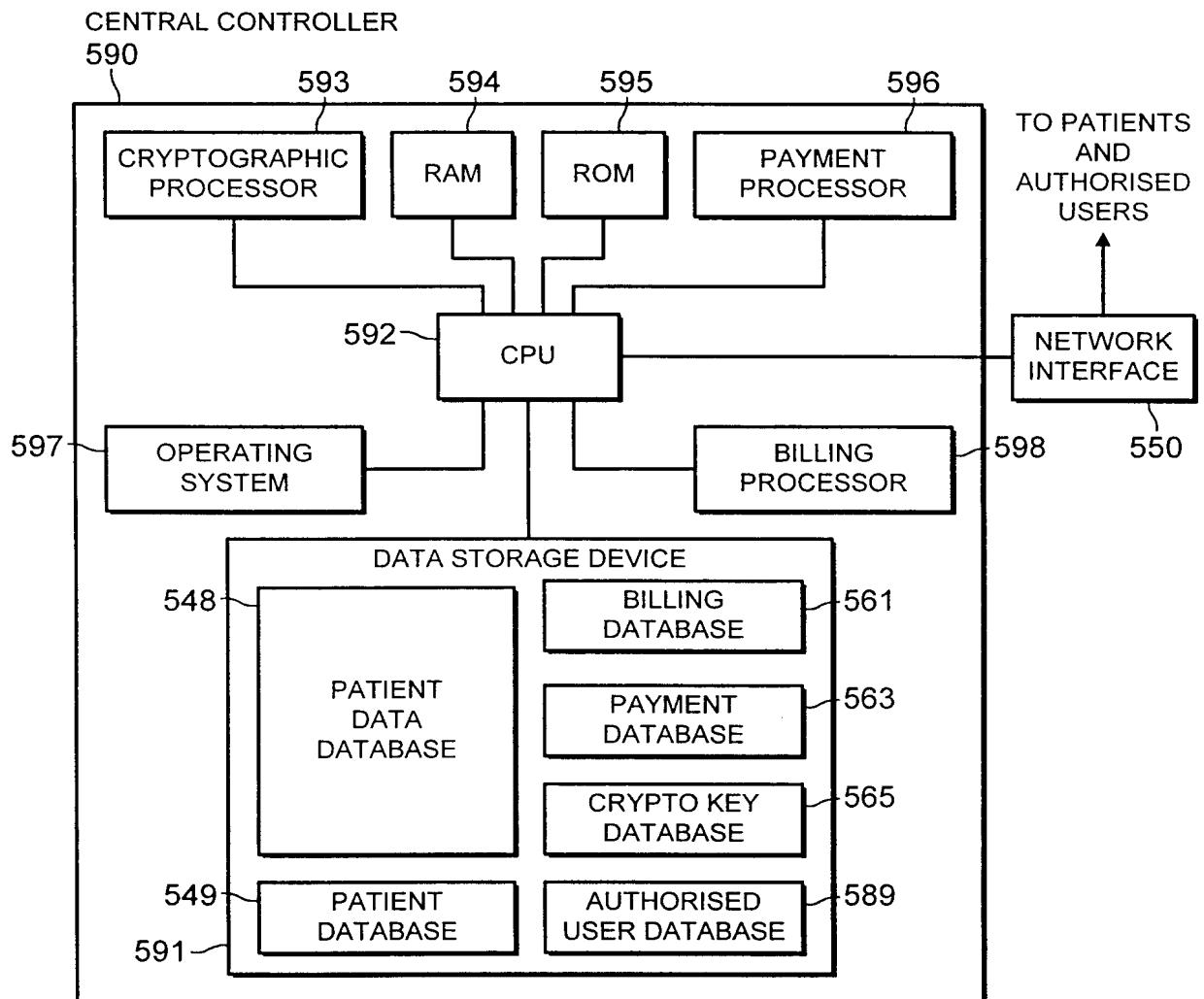


FIG. 6

5 / 5

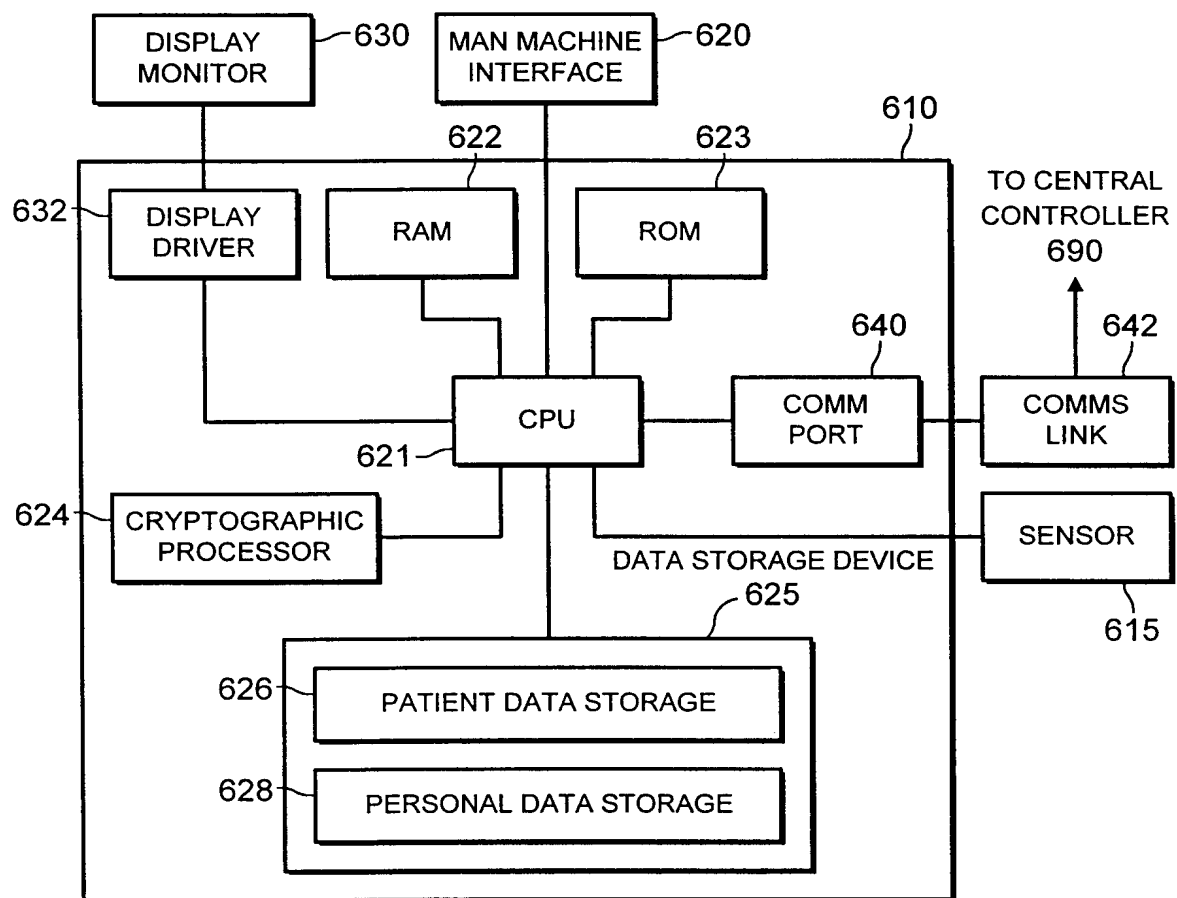


FIG. 7

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 April 2001 (12.04.2001)

PCT

(10) International Publication Number
WO 01/24690 A3

(51) International Patent Classification⁷: **G06F 19/00**,
A61B 5/00

(21) International Application Number: PCT/EP00/09291

(22) International Filing Date:
22 September 2000 (22.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9923273.8 1 October 1999 (01.10.1999) GB
0011029.6 9 May 2000 (09.05.2000) GB
0020541.9 22 August 2000 (22.08.2000) GB

(71) Applicant (for all designated States except US): **GLAXO GROUP LIMITED** [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **ANDERSON,**

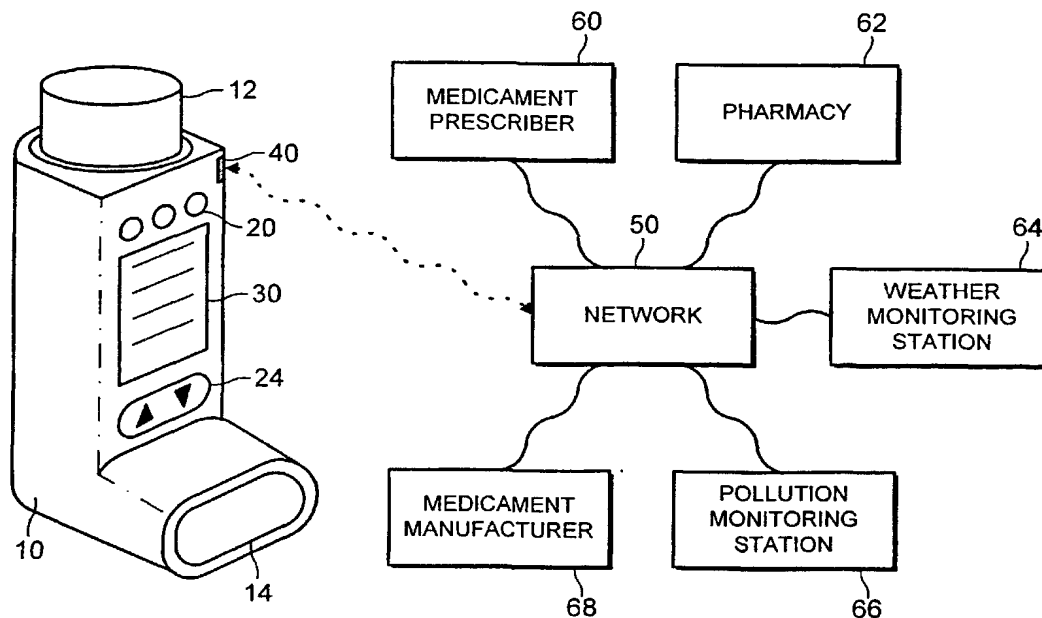
Gregor, John, McLennan [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts. SG12 ODP (GB). **BONNEY, Stanley, George** [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts. SG12 ODP (GB). **JONES, Anthony, Patrick** [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts. SG12 ODP (GB). **ROBERTSON, Duncan** [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts. SG12 ODP (GB).

(74) Agent: **PIKE, Christopher, Gerard**; Pike & Co., Hayes loft, 68A Hayes Place, Marlow, Buckinghamshire SL7 2BT (GB).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: MEDICAMENT DELIVERY SYSTEM



(57) Abstract: There is provided a system for the delivery of medicament comprising a medicament container; a dispensing mechanism for dispensing medicament from the medicament container; an electronic data management system; and a communicator for wireless communication with a network computer system to enable communication of data between the network computer system and the electronic data management system. The electronic data management system comprises a memory for storage of data; a microprocessor for performing operations on the data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.



(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

(88) Date of publication of the international search report:
10 May 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— with international search report

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/09291

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G06F19/00 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G06F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, COMPENDEX, IBM-TDB

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 10829 A (LARKINS WILLIAM T ;KAMEN DEAN L (US); MANNING ROBERT (US); NISBET) 4 March 1999 (1999-03-04) abstract page 1, line 1 -page 15, line 21 ---	1-51
X A	US 5 338 157 A (BLOMQUIST MICHAEL L) 16 August 1994 (1994-08-16) abstract column 1, line 1 -column 5, line 6 ---	1,50 2-49,51
X A	WO 99 41682 A (JOHNSON DAVID WAYNE ;SOUTHERN RES INST (US); DEAN ALAN HOYT (US);) 19 August 1999 (1999-08-19) the whole document --- -/--	1,50 2-49,51

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

4 February 2002

12/02/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Beltrán-Escavy, J

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/09291

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 924 074 A (EVANS JAE A) 13 July 1999 (1999-07-13) abstract column 1, line 1 -column 3, line 42 -----</p>	1-51

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 00/09291

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9910829	A	04-03-1999	AU 8909898 A WO 9910829 A1	16-03-1999 04-03-1999
US 5338157	A	16-08-1994	AU 693073 B2 AU 4840093 A AU 714459 B2 AU 6474498 A AU 6474598 A CA 2143436 A1 EP 1018347 A2 EP 0744973 A1 JP 8500515 T WO 9405355 A1 US 5485408 A US 6241704 B1 US 6024539 A	25-06-1998 29-03-1994 06-01-2000 02-07-1998 02-07-1998 17-03-1994 12-07-2000 04-12-1996 23-01-1996 17-03-1994 16-01-1996 05-06-2001 15-02-2000
WO 9941682	A	19-08-1999	AU 2762899 A WO 9941682 A2	30-08-1999 19-08-1999
US 5924074	A	13-07-1999	AU 4603497 A WO 9813783 A1	17-04-1998 02-04-1998